

REMARKS

STATUS OF THE CLAIMS

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35 and 38-47 were pending. Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 35 and 38-47 have been withdrawn from consideration and claim 34 has been examined. Applicants note that the Office Actions dated January 31, 2006 and November 15, 2005 do not show claims 39-47 as pending. Although claims 39-47 have been withdrawn from consideration, they have not been canceled.

Claim 34 was amended in the Response After Final to make explicit that the first or second polypeptide comprises a non-naturally occurring binding domain. An Advisory Action mailed on January 31, 2006 indicated that the amendments were not entered and that the pages cited in the Amendment After Final do not support a "non-naturally occurring Cys2-His2 DNA binding domain." (Advisory Action, continuation of box 3).

As previously indicated, Applicants note that support for the amendment to claim 34 can be found on page 3, lines 28-32 and page 12, lines 7-16, which provide general definitions for the terms "non-naturally occurring" and "domain." In addition, Applicants direct the Examiner's attention to page 23, lines 13-16 and page 24, lines 18-24, which clearly indicate that Applicants contemplated using non-naturally occurring Cys₂His₂ DNA binding domains as DNA binding molecules:

Thus, in one embodiment, the invention provides a method for preparing a DNA binding polypeptide of the Cys2-His2 zinc finger class capable of binding to a target DNA sequence, wherein binding is via a zinc finger DNA binding motif of the polypeptide and wherein said binding is modulatable by a ligand....

The present invention may be integrated with the rules set forth for zinc finger polypeptide design in our copending European or PCT patent applications having publication numbers; WO 98/53057; WO 98/53060; WO 98/53058, WO 98/153059, describe improved techniques for designing zinc finger polypeptides capable of binding desired nucleic acid sequences. In combination with selection procedures, such as phage display, set forth for example in WO 96/06166, these techniques enable the production of zinc finger polypeptides capable of recognising practically any desired sequence.

Additional support is found at page 23, lines 25-27. Thus, support for the amendment to claim 34 can be found throughout the specification as filed and entry thereof is requested.

By virtue of this Response, new claims 48 and 49 are added. Support for claim 48 is found, for example, at page 2, lines 21-24; page 27, lines 26-28; page 29, lines 4-5 and page 29, lines 20-24. Support for claim 49 is found, for example, at page 20, lines 5-19; page 29, lines 20-24 and page 26, lines 4-32 (see especially lines 22-23). Inasmuch as they recite switching system compositions, claims 48 and 49 are believed to fall within Group III as set forth in the Office Action dated March 18, 2004, and therefore can be examined along with claim 34.

Accordingly, claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35 and 38-49 are pending and claims 34, 48 and 49 are under consideration.

RESTRICTION REQUIREMENT

Applicants reiterate their request for rejoinder of method claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-24, 31, 35, 38-42, 46 and 47 upon allowance of claim 34.

REJECTIONS WITHDRAWN

Applicants note with appreciation that the rejections of claim 34 under 35 U.S.C. § 112 (new matter) and § 102 based on McEwan have been withdrawn. With respect to the new matter rejection, Applicants appreciate the Examiner's noting on the record that the recitation that the ligand binds to both the first and second polypeptides of the system did not constitute new matter.

35 U.S.C. § 101

Examined claim 34 was rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. *See* page 3 of the Final Office Action. In particular, previous amendment of the claim to remove the process steps was alleged to make the claim indistinguishable from naturally occurring switching systems. *Id.*

Claim 34 has been amended as shown above to indicate that the first or second polypeptide comprises a non-naturally occurring binding domain, as described throughout the specification as filed, for example on page 3, lines 28-32; page 12, lines 7-16; page 23, lines 13-16 and page 24, lines 18-24. Accordingly, claim 34 indicates the "hand of man" and the rejection can be properly withdrawn.

Similarly, new claims 48 and 49 recite engineered and mutant zinc finger proteins, respectively, thereby distinguishing them over naturally-occurring molecules.

35 U.S.C. § 102

Examined claim 34 was rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Porter (1997); Kobayashi (1996); and Perkins (1993). *See* pages 4-7 of the Final Office Action. These references are cited for teaching complexes of the naturally occurring C₂H₂ zinc finger protein Sp1. Porter, in view of Pratt (1997), is stated to teach complexes between Sp1 and ER whose formation is modulated by estrogen. Kobayashi is stated to teach complexes between Sp1, AhR, and Arnt whose formation is modulated by 3-MC. Perkins, in view of Prosite Database entry PDOC00028, is stated to teach complexes between Sp1 and NF-κB whose formation is modulated by TNFα or PMA. All of these complexes include the Sp1 protein, which comprises a naturally-occurring Cys2-His2 zinc finger binding domain.

By contrast, claim 34 is drawn to a switching system in which the first or second polypeptide comprises a non-naturally occurring Cys2-His2 zinc finger binding domain. None of the references disclose proteins comprising such non-naturally occurring Cys2-His2 zinc finger binding domains and, accordingly, withdrawal of this rejection is respectfully requested.


Similarly, the engineered and mutated zinc finger proteins recited in claims 48 and 49 are distinct from the naturally-occurring Sp1 protein disclosed in the references.

CONCLUSION

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, he is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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